

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

| | | |
|---------------------------------|---|---|
| ANDREA CAMERON, <i>et al.</i> , |) | CASE NO. 1:10 CV 2258 |
| |) | |
| Plaintiffs, |) | JUDGE DONALD C. NUGENT |
| |) | |
| v. |) | MAGISTRATE JUDGE |
| |) | WILLIAM H. BAUGHMAN, JR. |
| BOSTON SCIENTIFIC CORPORATION, |) | |
| |) | <u>REPORT & RECOMMENDATION</u> |
| Defendant. |) | |

Introduction

Before me by referral¹ in this matter, involving a *pro se* suit by Andrea and Gregory Cameron (the Camerons) against Boston Scientific Corporation (BSC) for damages arising from the use of a BSC medical device in the treatment of Andrea Cameron,² is BSC's motion for summary judgment under Federal Rule of Civil Procedure 56(b).³ The Camerons have responded to the motion,⁴ to which BSC has replied.⁵ For the reasons that follow, I will recommend that the motion be granted.

¹ ECF # 5.

² ECF # 1.

³ ECF # 15.

⁴ ECF # 17.

⁵ ECF # 18.

Facts

The facts relevant to the present motion are not extensive, and, as required, the Court must view those facts in the light most favorable to the Camerons. But, as will be more fully detailed below, critical portions of the plaintiffs' claims remain merely allegations without evidentiary support in the Rule 56 record.

The case involves a claim for damages arising from the use of a HydroThermAblator (HTA); a Class III medical device designed, manufactured, and sold by BSC under regulations administered by the United States Food and Drug Administration (FDA).⁶ BSC designed the HTA device to circulate heated saline in the uterus to eliminate or reduce menstrual bleeding, a minimally invasive alternative to a hysterectomy.⁷ The process, under the supervision of a physician, requires that: (a) the HTA sheath be inserted and sealed into the uterine cavity; (b) then saline circulates through the sheath and into the uterine cavity at increasing heat, ultimately reaching 90 degrees Celsius, which temperature is maintained for ten minutes; and finally (c) room temperature saline is used to flush and cool the treated area.⁸

⁶ ECF # 15 at 2-5, citing Affidavit of Lisa Movitz, Exhibit A ("HTA System User's Manual").

⁷ *Id.*

⁸ *Id.* at 2-3; ECF # 1 at ¶ 5.

Andrea Cameron received HTA treatment from her physician as an out-patient at the Cleveland Clinic in 2008.⁹ She alleged that her procedure “did not go as specified” by BSC in its literature.¹⁰ In particular, the complaint asserts that during “the heating and circulation phase of the procedure, the HTA malfunctioned and began leaking hot fluids,” resulting in burns to Cameron’s “vaginal introitus, her outer vaginal area, and buttocks.”¹¹

For its part, BSC states that “[o]ne of the risks associated with this procedure is a potential for leakage of hot fluid, which may result in thermal injury to surrounding tissue.”¹² To that point, BSC states that the HTA System User’s Manual and other literature explains this risk to patients.¹³ It also states that the FDA, through the pre-market approval (PMA) process, as well as the requirement for continued reporting of “adverse events,” has full responsibility for regulating the manufacture, sale, and marketing of the HTA device here.¹⁴ Thus, it contends, under the Medical Device Amendments (MDA) of 1976, as interpreted by the Supreme Court, the Camerons’ claims are preempted and that the Court should grant summary judgment for BSC.

⁹ ECF # 1 at ¶ 4.

¹⁰ *Id.* at ¶ 6.

¹¹ *Id.*

¹² ECF # 15 at 3 (internal citation omitted).

¹³ *Id.*

¹⁴ *Id.* at 12.

The Camerons, while agreeing that federal regulations govern the design, manufacture, and use of the HTA, assert that because BSC failed to comply with those regulations, the claims are not preempted.¹⁵ In particular, the complaint alleges that in January 2009, BSC recalled certain HTA units for a defect in the circuit board that could result in a failure of the system pump leading to patient injury from hot fluid leaks during the recirculating/heating phase of treatment.¹⁶ The complaint further maintains that the stated grounds for this recall are “consistent” with what happened to Andrea Cameron, and so BSC, in effect, failed to follow controlling federal regulations by not recalling the HTA unit used for Andrea Cameron’s procedure.¹⁷

Analysis

A. Standard of review – summary judgment

Summary judgment is appropriate where the court is satisfied “that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.”¹⁸ The burden of showing the absence of any such “genuine issue” rests with the moving party:

¹⁵ ECF # 1 at ¶ 8.

¹⁶ *Id.* at ¶ 7.

¹⁷ *Id.*

¹⁸ Fed. R. Civ. P. 56(c).

[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions answers to interrogatories, and admissions on file, together with affidavits, if any,’ which it believes demonstrates the absence of a genuine issue of material fact.¹⁹

A fact is “material” only if its resolution will affect the outcome of the lawsuit.²⁰ Determination of whether a factual issue is “genuine” requires consideration of the applicable evidentiary standards.²¹ The court will view the summary judgment motion “in the light most favorable to the party opposing the motion.”²²

Summary judgment should be granted if a party who bears the burden of proof at trial does not establish an essential element of his case.²³ Accordingly, “[t]he mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.”²⁴ Moreover, if the evidence presented is “merely colorable” and not “significantly probative,” the court may decide the legal issue and grant summary judgment.²⁵

¹⁹ *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (citing Fed. R. Civ. P. 56(c)).

²⁰ *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986).

²¹ *Id.* at 252.

²² *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

²³ *McDonald v. Petree*, 409 F.3d 724, 727 (6th Cir. 2005) (citing *Celotex Corp.*, 477 U.S. at 322).

²⁴ *Leadbetter v. Gilley*, 385 F.3d 683, 689 (6th Cir. 2004) (quoting *Anderson*, 477 U.S. at 248-49).

²⁵ *Anderson*, 477 U.S. at 249-50 (citation omitted).

In most civil cases involving summary judgment, the court must decide “whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict.”²⁶ But, if the non-moving party faces a heightened burden of proof, such as clear and convincing evidence, it must show that it can produce evidence which, if believed, will meet the higher standard.²⁷

Once the moving party has satisfied its burden of proof, the burden then shifts to the nonmover.²⁸ The nonmoving party may not simply rely on its pleadings, but must “produce evidence that results in a conflict of material fact to be solved by a jury.”²⁹ The text of Fed. R. Civ. P. 56(e) states:

When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial.

“In other words, the movant can challenge the opposing party to ‘put up or shut up’ on a critical issue.”³⁰

Though parties must produce evidence in support of and in opposition to a motion for summary judgment, not all types of evidence are permissible. The Sixth Circuit has

²⁶ *Id.* at 252.

²⁷ *March v. Levine*, 249 F.3d 462, 471 (6th Cir. 2001).

²⁸ *Anderson*, 477 U.S. at 256.

²⁹ *Cox v. Kentucky Dep’t of Transp.*, 53 F.3d 146, 149 (6th Cir. 1995).

³⁰ *BDT Prods. v. Lexmark Int’l*, 124 F. App’x 329, 331 (6th Cir. 2005).

concurred that “it is well settled that only admissible evidence may be considered by the trial court in ruling on a motion for summary judgment.”³¹ Rule 56(e) also has certain, more specific requirements:

[it] requires that affidavits used for summary judgment purposes be made on the basis of personal knowledge, set forth admissible evidence, and show that the affiant is competent to testify. Rule 56(e) further requires the party to attach sworn or certified copies to all documents referred to in the affidavit. Furthermore, hearsay evidence cannot be considered on a motion for summary judgment.³²

The district court nevertheless may consider evidence not meeting this standard unless the opposing party affirmatively raises the issue of the defect. The opposing party has the burden to object to the improper evidence; failure to object constitutes a waiver.

If a party fails to object before the district court to the affidavits or evidentiary materials submitted by the other party in support of its position on summary judgment, any objections to the district court’s consideration of such materials are deemed to have been waived, and [the Sixth Circuit] will review such objections only to avoid a gross miscarriage of justice.³³

As a general matter, the judge considering a motion for summary judgment is to examine “[o]nly disputes over facts that might affect the outcome of the suit under governing law.”³⁴ The court will not consider non-material facts, nor will it weigh material evidence

³¹ *Wiley v. United States*, 20 F.3d 222 (6th Cir. 1994) (quoting *Beyene v. Coleman Sec. Servs.*, 854 F.2d 1179, 1181 (9th Cir. 1988)).

³² *Id.* at 225-26 (citations omitted).

³³ *Id.* at 226 (citations omitted).

³⁴ *Anderson*, 477 U.S. at 248.

to determine the truth of the matter.³⁵ The judge's sole function is to determine whether there is a genuine factual issue for trial; this does not exist unless "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party."³⁶

In sum, proper summary judgment analysis entails:

the threshold inquiry of determining whether there is the need for a trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.³⁷

B. Application of standard – although *Hughes v. Boston Scientific Corporation* provides that the claims at issue are not preempted, the absence of any Rule 56 record to support the allegations requires summary judgment for BSC.

Resolution of the motion here turns on two very narrow questions: (1) whether such claims the Camerons alleged here are preempted, and (2) whether the Camerons have created a Rule 56 record sufficient to avoid summary judgment.

As to those issues, I will initially discuss the 2011 decision of the Fifth Circuit in *Hughes v. Boston Scientific Corporation*,³⁸ a citation that serves as the sole argument raised in the Camerons' response to BSC's motion for summary judgment.³⁹ *Hughes* holds that state-law claims also alleging violations of the federal regulations on medical devices are not

³⁵ *Id.* at 249.

³⁶ *Id.*

³⁷ *Id.* at 250.

³⁸ *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011).

³⁹ ECF # 17 at 1.

preempted. Next, I will I recommend concluding that *Hughes* correctly states the governing law. Finally, I will consider the arguments raised by BSC as understood in light of *Hughes* and the Rule 56 standard, and why, under those rubrics, I recommend deciding that BSC should receive summary judgment.

1. Hughes v. Boston Scientific Corporation

Hughes, as here, involved a personal injury claim arising out of an HTA treatment that allegedly produced burns from the leak of hot fluids.⁴⁰ As here, the *Hughes* plaintiff's state law claim rested on theories of product liability, breach of warranty, negligence, breach of implied warranty of merchantability, and of fitness for a particular purpose.⁴¹ *Hughes*, in addition, contended that BSC "failed to comply with the FDA's MDR regulations requiring a manufacturer of a Class III device to report incidents in which the device may have caused or contributed to a death or serious injury, or malfunctioned in such a way that would likely cause or contribute to death or serious injury if the malfunction recurred."⁴²

As concerns this last argument, the plaintiff in *Hughes* asserted that evidence obtained during discovery showed that BSC "developed an 'algorithm' regarding reportable events caused by the HTA according to which [BSC] reported some, but not all burns," caused by malfunctions of the HTA.⁴³ *Hughes* further argued that in 2008 the FDA directed BSC to

⁴⁰ *Hughes*, 631 F.3d at 765.

⁴¹ *Id.*

⁴² *Id.* at 765-66.

⁴³ *Id.* at 766.

“abandon the algorithm and to begin reporting more burns caused by the HTA.”⁴⁴ In addition, Hughes maintained that after this change in reporting requirements in 2008, there was “a sharp increase” during the period 2008-2009 in the number of reports of leaks or burn-related injuries concerning the HTA.⁴⁵

The district court granted BSC’s motion for summary judgment on the grounds, also asserted here, that the claims were preempted by the Supreme Court’s holdings in *Riegel v. Medtronic, Inc.*⁴⁶ and *Buckman v. Plaintiffs’ Legal Committee*.⁴⁷ The Fifth Circuit, however, after applying *Riegel* and *Buckman*, disagreed.

Initially, the Fifth Circuit stated the rule from *Riegel* and *Buckman* to be that a medical device manufacturer is protected from liability under state-law tort claims related to a defective or dangerous device “to the extent that the manufacturer has complied with federal statutes and regulations.”⁴⁸ Stated differently, *Hughes* held that a medical device manufacturer “is not protected from state tort liability when the claim is based on the manufacturer’s violation of applicable federal requirements.”⁴⁹

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

⁴⁷ *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001).

⁴⁸ *Hughes*, 631 F.3d at 767.

⁴⁹ *Id.*

Accordingly, in light of the above-stated rules, the *Hughes* court found first that all of the state-law claims against BSC that purport to impose liability on BSC notwithstanding BSC's compliance with applicable FDA regulations are expressly preempted.⁵⁰ The court also concluded, that "[t]o the extent that Hughes asserts a failure to warn claim based only on [BSC's] failure to comply with FDA regulations, however, such a claim is not expressly preempted."⁵¹ In that regard, *Hughes* determined, based on authority such as the Sixth Circuit's decision in *Howard v. Sulzer Orthopedics, Inc.*,⁵² and the Seventh Circuit's conclusions in *Bausch v. Stryker Corp.*,⁵³ that claims for negligent failure to warn or negligent manufacturing of a medical device are not preempted to the extent that a plaintiff asserts that the manufacturer violated the state duties involved by virtue of its failure to comply with the applicable federal regulations.⁵⁴

The decision of the Seventh Circuit in *Bausch* provides guidance for the application of *Hughes* here. Relevant to the analysis of this case, the Seventh Circuit in *Bausch* examined the Eighth Circuit decision in *In re Medtronic, Inc., Sprint Fidelis Leads Product*

⁵⁰ *Id.* at 768.

⁵¹ *Id.* at 769.

⁵² *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440-42 (6th Cir. 2010) (unpublished).

⁵³ *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010).

⁵⁴ *Hughes*, 631 F.3d at 770.

Liability Litigation.⁵⁵ There, a divided panel of the Eighth Circuit affirmed a dismissal of plaintiffs’ manufacturing defect claims on the grounds that the claims “as pleaded and argued”⁵⁶ to the district court were both expressly preempted under *Riegel* and impliedly preempted under *Buckman*.⁵⁷ Specifically, the *Medtronic Leads* opinion, as quoted by the Seventh Circuit in *Bausch*, held that the “plaintiff must be suing for conduct that *violates* the [Food, Drug and Cosmetic Act] (or else his claim is expressly preempted by § 306(a)), but the plaintiff must not be suing *because* the conduct violates the [Food, Drug and Cosmetic Act] (such a claim would be impliedly preempted under *Buckman*.”)⁵⁸

In the end, the *Bausch* court concluded, where a plaintiff “claims breach of a well-recognized duty owed to her under state law,” such a claim may proceed “as long as she can show that she was harmed by a violation of applicable federal law. Her claim is not impliedly preempted by federal law.”⁵⁹

⁵⁵ *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litigation*, 623 F.3d 1200 (8th Cir. 2010).

⁵⁶ *Id.* at 1207.

⁵⁷ *See, id.* at 1204. There is a “narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption.”

⁵⁸ *Bausch*, 630 F.3d at 557-58 (quoting *Medtronic Leads*, 623 F.3d at 1204 (emphasis in original)).

⁵⁹ *Id.* at 558.

2. BSC's arguments

BSC asserts that the Camerons make only “one single allegation” in their complaint at paragraph 27 concerning a failure of BSC to comply with federal reporting regulations,⁶⁰ and insufficiently plead allegations of a failure to warn at paragraphs 10, 11, 14, 15, and 20.⁶¹ BSC further argues that the Camerons have not presented any Rule 56 evidence regarding the failure to warn claim such that it can survive summary judgment.⁶² Finally, BSC contends that the *Hughes* case is “not applicable” because the Camerons have presented no evidence that BSC violated any federal requirements or failed to report any serious injuries or malfunctions.⁶³

I note first, as did the Seventh Circuit in *Bausch*,⁶⁴ that:

There are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular. The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new “plausibility” standard applied in *Iqbal*⁶⁵ and *Twombly*.⁶⁶

⁶⁰ ECF # 18 at 2-3.

⁶¹ *Id.* at 4-6.

⁶² *Id.* at 6-7.

⁶³ *Id.* at 7.

⁶⁴ *Bausch*, 630 F.3d at 558.

⁶⁵ *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

⁶⁶ *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

In applying that standard to claims for defective manufacture of a medical device in violation of federal law, however, the *Bausch* decision further notes that:

[D]istrict courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. *Formal discovery is necessary before a plaintiff can be expected to provide a detailed statement of the specific bases for her claim.*⁶⁷

Here, without now directly addressing BSC's assertions concerning the sufficiency of the pleading, I note that the Camerons have conducted no discovery under the case management plan filed in this case. Indeed, despite being informed at the initial case management conference in November, 2010, that BSC planned to file a dispositive motion in this matter,⁶⁸ plaintiffs permitted the discovery deadline⁶⁹ to pass without filing any discovery and also failed to participate in the telephonic status conference held immediately after BSC filed the present motion.⁷⁰

As such, as mentioned earlier, the Camerons's response to the present motion contained no Rule 56 evidence of any kind. In addition, the plaintiffs made no effort to revise or modify the case management plan. While mindful that pleadings from a *pro se*

⁶⁷ *Bausch*, 630 F.3d at 558 (emphasis added).

⁶⁸ *See*, non-document order of November 19, 2010.

⁶⁹ ECF # 11 (case management plan and order requiring discovery to be conducted by July 7, 2011).

⁷⁰ ECF # 16 (minutes of telephonic status conference of Jan. 25, 2011).

plaintiff are to be accorded leniency, such leniency “is not boundless.”⁷¹ In this case, while acknowledging that the Camerons are correct that a claim such as theirs would likely not be preempted under the authority detailed above, leniency does not permit the Court to overlook the fact that the allegations have not been supported in any way by the submission of any evidence that could be construed favorable to the Camerons and so deny BSC’s motion.⁷²

Identifying the correct roadmap is not sufficient of itself to reach a destination; there must also be an adequate vehicle by which to make the journey.

Conclusion

Accordingly, for the reasons set forth above, I recommend that the motion for summary judgment by defendant BSC be granted.

Dated: April 12, 2012

s/ William H. Baughman, Jr.
United States Magistrate Judge

Objections

Any objections to this Report and Recommendation must be filed with the Clerk of Courts within fourteen (14) days of receipt of this notice. Failure to file objections within the specified time waives the right to appeal the District Court’s order.⁷³

⁷¹ *Martin v. Overton*, 391 F.3d 710, 713 (6th Cir. 2004).

⁷² I note here that in *Hughes*, the case on which the Camerons rely, the plaintiff was successful in defeating the summary judgment motion there because of the evidence she submitted in response to the motion. *See, Hughes*, 631 F.3d at 766-67.

⁷³ *See, United States v. Walters*, 638 F.2d 947 (6th Cir. 1981). *See also, Thomas v. Arn*, 474 U.S. 140 (1985), *reh’g denied*, 474 U.S. 1111 (1986).